

#### § 405.430

beneficiary (or legal representative) has privately contracted.

(i) The physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act may order, certify the need for, or refer a beneficiary for Medicare-covered items and services, provided the physician or practitioner is not paid, directly or indirectly, for such services (except as provided in § 405.440).

(j) The physician or practitioner who is excluded under sections 1128, 1156, or 1892 of the Social Security Act may not order, prescribe, or certify the need for Medicare-covered items and services except as provided in § 1001.1901 of this title, and must otherwise comply with the terms of the exclusion in accordance with § 1001.1901 effective with the date of the exclusion.

#### § 405.430 Failure to properly opt-out.

(a) A physician or practitioner fails to properly opt-out if—

(1) Any private contract between the physician or practitioner and a Medicare beneficiary, that was entered into before the affidavit described in § 405.420 was filed, does not meet the specifications of § 405.415; or

(2) He or she fails to submit the affidavit(s) in accordance with § 405.420.

(b) If a physician or practitioner fails to properly opt-out in accordance with paragraph (a) of this section, the following results obtain:

(1) The physician's or practitioner's attempt to opt-out of Medicare is nullified, and all of the private contracts between the physician or practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt-out are deemed null and void.

(2) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician is subject to the limiting charge provisions of § 414.48 of this chapter. A participating physician is subject to the limitations on charges of the participation agreement he or she signed.

(3) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

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(4) The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts.

(5) The physician or practitioner may make another attempt to properly opt-out at any time.

#### § 405.435 Failure to maintain opt-out.

(a) A physician or practitioner fails to maintain opt-out under this subpart if, during the opt-out period—

(1) He or she knowingly and willfully—

(i) Submits a claim for Medicare payment (except as provided in § 405.440); or

(ii) Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in § 405.440).

(2) He or she fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into contracts that fail to meet the specifications of § 405.415; or

(3) He or she fails to comply with the provisions of § 405.440 regarding billing for emergency care services or urgent care services; or

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

(b) If a physician or practitioner fails to maintain opt-out in accordance with paragraph (a) of this section, and fails to demonstrate, within 45 days of a notice from the carrier of a violation of paragraph (a) of this section, that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract), the following results obtain, effective 46 days after the date of the notice, but only for the remainder of the opt-out period:

(1) All of the private contracts between the physician or practitioner and Medicare beneficiaries are deemed null and void.